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| 09/972,469 | 10/05/2001 | Fang Lai | SP01-290 | 4187 |
| 22928 | 7590 | 05/02/2007 | | |
| CORNING INCORPORATED | | | EXAMINER | |
| SP-TI-3-1 | | | SMITH, CAROLYN L | |
| CORNING, NY 14831 | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |
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| | | | 05/02/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/972,469

Applicant(s)

LAI ET AL.

Examiner

Carolyn L. Smith

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) 29-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments and remarks, filed 6/27/05, are acknowledged. Amended claims 1-5, 11-12, and 27, canceled claims 13-26, and new claims 28-34 are acknowledged.

Newly submitted claims 29-34 are directed to an invention that is independent or distinct from the elected invention originally claimed for the following reasons: Claims 29-34 are drawn to a method of making a DNA array which contains distinct goals and steps that differ from the elected invention of a method for amplifying expressed genetic sequences from genomic DNA. The distinct goals and steps document the divergent subject matter and resulting undue search burden if these groups were searched together. These methods have acquired a separate status in the art because of their recognized divergent subject matter. Therefore, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally elected invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29-34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's arguments, filed 6/27/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The petition to revive this application was granted, mailed 3/29/05.

Claims 1-12 and 27-28 are herein under examination.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. These rejections are necessitated by amendment.

Claim 1 (last two lines) and 28 (last line) recite the phrase “to a substrate of an array” which is vague and indefinite. It is unclear if the substrate is the array itself or if the substrate is something attached to an array. Clarification of this issue via clearer claim wording is requested. Claims 2-12 and 27 are also rejected due to their dependency from claim 1.

Claims 2, 3, and 11 recite the phrases “said amplified sequence” or “said amplified sequences” which lack clear antecedent basis. It is noted that claim 1, from which claims 2, 3, and 11 depend, contains two polymerase chain reactions which both result in amplified sequences. It is therefore unclear if the phrase in claims 2, 3, and 11 is referring to the amplified sequence from the first or second PCRs. Clarification of this issue via clearer claim wording is requested.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 5-10, 12, and 27-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Keating et al. (P/N 6,274,332). This rejection is necessitated by amendment.

Keating et al. disclose a method for amplifying exons (expressed genetic sequences) from human genomic DNA (higher-order eukaryotic species) (abstract; col. 2, lines 42-44; and col. 46, lines 60-62). Keating et al. disclose using screening methods to determine if a trapped exon was part of a gene (col. 46, lines 58-59). Keating et al. disclose screening alleles after cloning with various techniques including DNA microchip technology (DNA microarray) (col. 12, lines 20-26 and col. 40, lines 11-33). Keating et al. disclose identifying a 3' UTR based on the presence of a stop codon and polyadenylation signal in the sequence (Figures 5A-B; stop codon denoted with asterisk; col. 5, paragraph 5). Keating et al. disclose identifying polyadenylation signals upstream to the 3'untranslated region with the longest open reading frame being 1654 base pairs of cDNA (col. 47, lines 1-5) which represents a length of at least about 75 nucleotides (instant claim 5), about 200 to 600 bases (instant claim 6), and about 250 to about 450 bases (instant claim 7), and up to about 2000 nucleotides (instant claim 27). Keating et al. disclose using probes to select all or specific regions of KVLQT1 or KCNE1 and screening the whole mRNA (which contains 3'UTR and exons) (col. 21, second and third paragraphs; col. 11, third paragraph; Tables 3 and 8) which encompasses selecting a predetermined sequence within the

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3'UTR or exon and designing probes. Keating et al. disclose using probes to amplify exons, genomic KCNE1 and cDNA, amplifying a portion of a gene, and providing a set of primers (probes) for amplification of said portion (col. 8, lines 1-26 and 47-55; col. 10, lines 55-58; and col. 21, lines 10-12). Keating et al. disclose designing such primers (col. 13, lines 47-49). Keating et al. disclose an identification of exons in Figure 2 (col. 5, lines 23-24). Keating et al. disclose amplifying genomic samples by PCR using primer pairs (col. 56, lines 39-52). Keating et al. disclose amplifying exons on genomic clones, characterizing PCR products, DNA sequencing, and database analyses to reveal 8 exons with similarity to ion channels (col. 46, lines 39-57). Keating et al. disclose performing electrophoreses and cutting out SSCP bands (selected predetermined bands) from the gels to be reamplified (second PCR), products were separated and DNA was sequenced (col. 56, line 53 to col. 57, line 12) as well as chromatographic techniques (col. 23, third paragraph). Keating et al. disclose that the nucleic acids of their invention possess a sequence with substantial homology with a natural KVLQT1- or KCNE1-encoding gene or a portion thereof (col. 17, lines 1-5). It is noted that the "less than" terminology in instant claims 8 and 9 can include 0%, such that the substantial homology described above represents "homology of less than or equal to about" 40% or 70% as stated in instant claims 8 and 9. It is noted that the terminology "about 20% to 30%" in instant claim 10 can be reasonably and broadly interpreted to be encompassed by the "substantial homology" disclosure as stated above by Keating et al. Keating et al. disclose using nucleic acid microchips (col. 12, lines 20-30) which represents a deposition of sequences on a substrate in an array, as stated in instant claims 1 and 2. Keating et al. disclose this method is one of parallel processing at once (col. 12, lines 30-42) which represents a rectilinear format, as stated in instant claim 12.

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Thus, Keating et al. anticipate the limitations in claims 1-2, 5-10, 12, and 27-28.

Applicants argue that Keating et al. fail to teach amplifying genomic sequences from the 3'UTR regions or depositing amplified sequences to a substrate. These statements are found unpersuasive as Keating et al. disclose using probes to select all or specific regions of KVLQT1 or KCNE1 and screening the whole mRNA (which contains 3'UTR and exons) (col. 21, second and third paragraphs; col. 11, third paragraph; Tables 3 and 8) which encompasses selecting a predetermined sequence within the 3'UTR or exon and designing probes. Keating et al. disclose screening alleles after cloning with various techniques including DNA microchip technology (DNA microarray) (col. 12, lines 20-30 and col. 40, lines 11-33). Applicants' arguments are deemed unpersuasive for the reasons given above.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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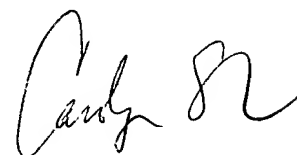
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

April 26, 2007

A handwritten signature in black ink, appearing to read 'Carolyn Smith', with a stylized flourish at the end.

Carolyn Smith
Examiner
AU 1631